



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker Endoscopy
Mr. Kiran Javadekar
Senior Design Engineer
5900 Optical Court
San Jose, CA 95138

JUL 27 2015

Re: K022393
Trade/Device Name: Merdoc™ System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, HRX
Dated (Date on orig SE ltr): March 31, 2003
Received (Date on orig SE ltr): April 1, 2003

Dear Mr. Javadekar,

This letter corrects our substantially equivalent letter of June 5, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

June 3, 2003

510(k) Number (if known): K022393

Device Name: Sidne™

Indications for Use:

The Stryker Sidne™ System is indicated for use with compatible endoscopic and general surgery devices. The Stryker Sidne™ System can be used in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope /endoscope/arthroscope is indicated for use. A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic anterior spinal fusion, anterior cruciate ligament reconstruction, knee arthroscopy, shoulder arthroscopy, small joint arthroscopy, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement. The users of Sidne™ are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, and urologists.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022393

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐

K022393

JUN - 5 2003

stryker
ENDOSCOPY

5900 Optical Court
San Jose, CA 95138
(408) 754-2000
Fax (408) 754-2505

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name: Laparoscope, General and Plastic Surgery

Common and Usual Name: Sidne™

Proprietary Name: Sidne™ System

This 510(k) summary and effectiveness is being submitted in accordance with requirements of SMDA 1990


The Sidne™ System is substantially equivalent in safety and efficacy as the currently marketed HERMES OR Control Center. The HERMES OR Control Center was cleared under 510K# 991444.

The Stryker Sidne™ System is a medical device that is designed to allow the surgeon to control the state, selection, and settings of the surgical equipment it is networked with. Sidne™ is compatible with existing devices that are HERMES OR Control Center compatible.

The intent of the Sidne™ Control Center is to allow for voice control of medical device settings by the surgeon or operating room personnel, thereby eliminating the need for manual operation of those devices compatible with Sidne™, or relying upon verbal communications between the surgeon and other personnel in the operating room in order to adjust the surgical equipment. The Sidne™ System is intended for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope /endoscope/arthroscope is indicated for use.

The Sidne™ System conforms to the following voluntary standards: EN 60601-1-1 Medical Electrical Equipment Part 1: General Requirements for Safety; EN 60601-1-1 Collateral Standard: Safety Requirements for Medical Electrical Systems; EN 60601-1-2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests; EN 60601-1-4 Collateral Standard: Programmable Electrical Medical Systems.

The technological differences between the Stryker Sidne™ System and the predicate HERMES device do not raise new issues of safety and efficacy of the predicate device. Therefore, the Stryker Sidne™ System is substantially equivalent to the currently marketed Computer Motion HERMES™ OR Control Center.


Kiran Javadekar
Senior Design Engineer
Stryker Endoscopy

Date: 6/03/2003